



Purpose of Proposed Rule Microbial & Biochemical (40 CFR Part 158)



US Environmental Protection Agency
Office of Pesticide Programs
Field and External Affairs Division

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Pesticide Data Requirements



Organization

- U.S. EPA Office of Pesticide Programs
 - Field & External Affairs Division
 - Coordination of regulation development
 - Registration Division & Science Divisions
 - Conventional chemical pesticides
 - Biopesticides & Pollution Prevention Division
 - multidisciplinary: Review Managers and Scientists
 - Microbial Pesticides – proposed data requirements
 - Biochemical Pesticides – proposed data requirements
 - Plant-Incorporated Protectants – new rule begun
 - www.epa.gov/pesticides/biopesticides





Team For Proposed Rule

- Field and External Affairs Division/OPP
 - Candy Brassard, Nathanael Martin, Jean Frane
- Biopesticides and Pollution Prevention Division/OPP
 - Bill Schneider, Bob Torla, John Kough, Zig Vaituzis, Roger Gardner, Russell Jones
- Office of General Counsel
 - Amber Aranda
- Office of Policy, Economics and Innovation
 - Kevin DeBell
- Office of Research and Development
 - Dennis Utterback
- Office of Enforcement and Compliance Assurance
 - Steve Howie



What Does the Law Require?

- Both FIFRA and FFDCA require submission of data to demonstrate standard is met
 - Standardized data requirements
 - Current provisions in Part 158 promulgated in 1984



Why Have EPA's Data Needs Changed Since 1984?

- 1988 FIFRA Amendments
- 1993 National Academy of Sciences Report
- 1994 Scientific Advisory Panel Review
- 1996 Food Quality Protection Act
- Pesticide Reregistration – ongoing



The Proposed Rule

- March 8, 2006 (71 FR 12072)
- 90 day comment period
- Public comments on or before June 6, 2006





Purposes of Proposed Rule

- Ensuring high quality data to meet EPA's mandates
- Ensuring a sound scientific basis that is consistent with advances in scientific understanding
- Works toward harmonization to avoid duplication
- Improving utility of part 158 data tables
- Reducing burdens where consistent with need for data



Benefits of the Proposal

- More refined risk assessments
 - Clearer understanding of the risk
 - Clarity and transparency
 - Reduces cost to regulated community
 - Enhanced international harmonization ultimately reduces duplication



EPA Activities in Preparation for this Rule

- Consideration in redesigning data tables
 - Various categories
 - Biochemicals, i.e., pheromones, plant growth regulators, repellents
 - Microbials, i.e., viruses, fungi, bacteria
- Evaluated consistencies between current practices and updated version
 - Data analysis conducted 1997-2004
 - Biochemicals
 - Microbials
- Consultations with stakeholders



Key Issues

- Revisions (explanation for changes)
 - Definitions, test notes, data required
- Biochemicals vs. Conventionals
 - Biochemical data requirements based on appropriate conventional data requirements
- Consultations with applicants:
 - Pre-submission
 - Post-submission



Key Areas We Invite Comment

- Revisions
 - Definitions, test notes, tiering scheme, etc.
- Consultation with applicants
- APHIS permit required as condition of registration for imported microbial pesticides
- Economic Analysis



What Types of Changes In Regulatory Text

- Newly imposed requirements
- Newly codified requirements
- Revision of existing requirements
- Elimination of requirements
- Revisions to the definitions for biochemical and microbial pesticides



How to Use Tables

- Use patterns - food/nonfood use
- Required (R) and conditionally required (CR)
- Test substances: (TGAI, EP, MP)
- Test notes describe conditions when data are required
- Guideline numbers
 - Harmonized with OECD numbers
- Experimental Use Permits: [CR], [R]



Part 158 Data Requirements vs Guidelines

- Part 158 data requirements
 - Mandatory
 - Data to address human health and environmental risk assessment
- Guidelines
 - Recommendations on study design
 - Peer reviewed protocols
 - Guidance on reporting of data



Reading A Table

TABLE—MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use patterns		Test substances to support		Test notes
		Food Use	Nonfood Use	MP	EP	
Product Chemistry and Composition						
885.1100	Product identity	[R]	[R]	MP	EP	—
885.1200	Manufacturing process	[R]	[R]	TGAJ and MP	TGAJ and EP	1,2
	Deposition of a sample in a nationally recognized culture collection	[R]	[R]	TGAJ	TGAJ	—
885.1300	Discussion of formation of unintentional ingredients	[R]	[R]	TGAJ and MP	TGAJ and EP	2



Summary

- The proposed rule is a team effort.
- Data requirements for microbial and biochemical pesticides last updated in 1984.
- Data analysis was conducted to validate the proposed rule.
- Agency invites constructive comments on proposed rule.

